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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,909	11/24/2003	Roland Janzen	DCS-9151	5291

34500 7590 02/08/2005

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EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,909	JANZEN ET AL.	
	Examiner	Art Unit	
	David J Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 19, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8 and 12-16, drawn to reagents, classified in class 252/398, for example.
- II. Claims 9-11 and 17-21, drawn to methods, classified in class 436/518, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of Invention I can be used in a materially different process, such as a process for assaying first binding species.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Agent LeLand Jordan on January 25, 2005, a provisional election was made without traverse to prosecute the Invention I, claims 1-8 and 12-16. Affirmation of this election must be made by Applicants in replying to this Office action. Claims 9-11 and 17-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

In claim 2, there is insufficient antecedent support for the recitation of "a defined binding surface."

In claim 4, there is insufficient antecedent support for the recitation of "bindable derivatives thereof."

In claim 7, there is insufficient antecedent support for the recitation of "a permeable material."

In claim 12, there is insufficient antecedent support for the recitation of "wherein the first portion of the first binding species and the second portion of the first binding species, when combined, make up approximately 100% of the known total amount of the first binding species."

In claim 13, there is insufficient antecedent support for the recitation of "wherein binding of the first binding species to said second substrate does not impair the binding of first binding species to a binding target."

In claim 14, there is insufficient antecedent support for the recitation of "a second substrate having... regions characterized by their ability to selectively bind first binding species associated with said first substrate."

The disclosure is further objected to for various informalities. Appropriate correction is required.

On page 12 of 23, paragraph [0039], the recitation of "lot 1053:89" is indefinite because it is not clear what dye, sensitizer, or bead is referenced.

In Tables 1-6, the recitation of "Level" is indefinite because it is not clear what "Level" is measured or the exact quantity or unit of measurement of the various "Levels"

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The specific claim rejections under 35 USC 112, second paragraph, set forth infra, may be considered relevant to other claims not explicitly mentioned, as deemed reasonably appropriate.

In claim 1, the recitation of "their" is indefinite because it is not clear what nouns "their" is referencing. In addition, the recitation of conditional language "if" does not create a positive or negative claim limitation and is indefinite. In addition, the recitation of "dissociated" is indefinite because it is not clear what noun(s) is/are "dissociated." In addition, claim 1 is indefinite because it is not clear how, or by what mechanism, a "region" can bind a binding species.

In claim 2, the recitation of "defined" is indefinite because it is not clear what parameters define a "defined" binding surface.

In claim 4, the recitation of "selected from the group essentially consisting of" is indefinite because it is not clear whether a Markush-type claim is intended. In addition, the recitation of "bindable derivatives thereof" is indefinite because it is not clear what binding species are referenced.

Claim 7 is indefinite because, it is not clear how, or by what mechanism, a "surface" has affinity for a binding species. In addition, the recitation of conditional language "when" does not create a positive or negative claim limitation and is indefinite. In addition, the recitation of "dissociated" is indefinite because it is not clear what parameters define a state of "dissociated" or what degree of dissociation is required by "dissociated."

In claim 12, the recitation of "the known total amount" lacks antecedent basis. In addition, claim 12 is indefinite because it is not clear how, or by what mechanism, a "region" can bind a binding species. In addition, the recitation of conditional language "when" does not create a positive or negative claim limitation and is indefinite. In addition, the recitation of "dissociated" is indefinite because it is not clear what parameters define a state of "dissociated" or what degree of dissociation is required by

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"dissociated." In addition, the recitation of "make up approximately 100% of the known total amount of the first binding species" is indefinite because it is not clear whether/how this language structurally limits Applicants' invention. In addition, the recitation of "adapted to" is indefinite because it is not clear what parameter(s) of "regions" is/are modified or what structure corresponds to said adaptation.

In claim 13, the recitation of "their" is indefinite because it is not clear what nouns "their" is referencing. In addition, the recitation of "impair" is indefinite because it is not clear how, or by what mechanism, binding is impaired, or what parameters define a state of impairment or what degree of impairment is required by "impair." In addition, claim 13 is indefinite because it is not clear how, or by what mechanism, a "region" can bind a binding species. In addition, the recitation of "wherein binding of first binding species to said second substrate does not impair the binding of first binding species to a binding target" is indefinite because it is not clear whether/how this language structurally limits Applicants' invention.

In claim 14, the recitation of "dissociated" is indefinite because it is not clear what parameters define a state of "dissociated" or what degree of dissociation is required by "dissociated." In addition, the recitation of "associated" is indefinite because it is not clear what parameters define a state of "associated" or what degree of association is required by "associated." In addition, claim 14 is indefinite because it is not clear how, or by what mechanism, a "region" can bind a binding species. In addition, the recitation of conditional language "if" does not create a positive or negative claim limitation and is indefinite. In addition, the recitation of "their" is indefinite because it is not clear what nouns "their" is referencing. In addition, the recitation of "wherein the second substrate binds..." is indefinite because it is not clear how, or by what mechanism, a "substrate" can bind to a first binding species, or whether said "regions" of the second substrate are responsible for binding, and, if so, which "regions" are responsible for binding. In addition, the recitation of "a plurality of first binding species to a common second substrate" lacks antecedent basis or is indefinite because it is not clear whether the second substrate also has the first binding species attached. In addition, the recitation of "a common second substrate" is indefinite because it is not clear whether said "common second substrate" corresponds to said "second substrate" or whether

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said "common second substrate" is a separate and distinct substrate. Assuming that said "common second substrate" is a separate and distinct entity from said "second substrate," it is not clear how, or by what mechanism, one substrate binds a plurality of binding species to another substrate. In addition, the recitation of "the plurality of first substrate" lacks antecedent basis. In addition, the recitation of "cross-linked" is indefinite because it is not clear which "binding species" or "regions" are responsible for said cross-linking, or whether "cross-linked" corresponds to binding between "regions" of the second substrate and dissociated "first binding species", or whether "cross-linked" corresponds to binding between "regions" of the second substrate and "first binding species" associated with said first substrate, or whether "cross-linked" corresponds to binding between "second substrate" and "plurality of first binding species."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman et al. (US 6,406,913).

Ullman et al. teach a reagent comprising a fluid medium (see col. 36, lines 1-32) containing a first substrate (see col. 19, lines 47-65) having a first binding species (see col. 14, lines 55-67) attached thereto (see col. 19, lines 66-67), and a second substrate having binding regions characterized by their ability to selectively bind said first binding species (see col. 35, lines 36-38, see col. 37, lines 28-35). The language "if dissociated from said first substrate" does not structurally differentiate Applicants' invention from the reagent of Ullman et al. because Examiner considers such language as functional in nature. See MPEP 2114.

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With respect to claims 2-3 and 15-16, Ullman et al. teach a reagent wherein the first substrate and second substrates are the same material or different material (see col. 21, lines 23-35).

With respect to claim 7, Ullman et al. teach a reagent comprising a permeable material (see col. 19, lines 47-48) including an inner surface having an affinity for said binding species (see col. 15, lines 38-40).

With respect to claim 12, Ullman et al. teach a reagent used in a sandwich type assay (see col. 35, lines 25-33) comprising a first binding species (see col. 37, lines 58+, "TSH"), wherein a first portion (see col. 38, lines 7-9) is attached to the first substrate and a second portion is dissociated from the first substrate, and the second portion binds to a second substrate. The language "wherein the first portion of the first binding species and the second portion of the first binding species, when combined, make up approximately 100% of the known total amount of the first binding species" does not structurally differentiate Applicants' invention from the reagent of Ullman et al. because Examiner considers such language as functional in nature. See MPEP 2114.

With respect to claim 13, the language "wherein binding of first binding species to said second substrate does not impair the binding of first binding species to a binding target" does not structurally differentiate Applicants' invention from the reagent of Ullman et al. because Examiner considers such language as functional in nature. See MPEP 2114.

With respect to claim 14, Ullman et al. teach a reagent wherein specific binding pair members are located on the surface (see col. 14, lines 55-56) of different supports (see col. 19, lines 47-65) and are used in a competitive assay format (see col. 35, lines 36-38, see col. 37, lines 28-35) wherein one binding member is complementary to the other binding member (see col. 37, lines 28-35). The claimed limitation of "wherein an aggregate is formed" is necessarily present in the teaching of Ullman et al. and would be so recognized by persons of ordinary skill in the art.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

djv



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02/04/05